GE Healthcare

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Certified Mail Return Receipt Requested

Important Electronic Product Radiation Warning

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

June 12, 2007

To:	**Hospital Administrator**
	Director/Manager of Radiology
Subject:	**Product Safety Issues**
Affected Products:	**OEC ® 9900 Elite** **OEC ® 9800** **OEC ® 8800** **OEC ® 6800** **OEC ® 2800**

Our records indicate that your facility currently has one or more of the products listed above.

GE Healthcare has identified an issue affecting these products as described below. This communication is intended to provide clarification on the prior communication dated April 2, 2007.

Failure to display Air Kerma and Cumulative Air Kerma:

A configuration issue has been discovered that results in the failure of the system to display the International Standard quantity, air kerma, to describe the radiation output. The usage of Air Kerma to replace entrance exposure, and the display of Air Kerma Rate and Cumulative Air Kerma are required on systems manufactured after June 10, 2006 by 21 CFR 1020.32(k). In GE OEC systems, AKR (air kerma rate) is calculated from technique factors (kVp, mA, and if pulsing, the duty factor.) CAK (cumulative air kerma) is calculated from the same, but accumulated over the duration of the procedure.

These systems, as shipped, did not meet the requirement of 21 CFR 1020.32(k), in that the systems were not configured to display Air Kerma Rate and Cumulative Air Kerma at the operators working position on individually distinguishable displays.

This issue does not impact the safety of operation of your system, however does result in non-compliance to 21CFR 1020.32 (k).

Your GEHC Surgery service representative will be contacting you in the near future to arrange for an inspection and to modify your system configuration if necessary to assure compliance with the requirements of 21 CFR 1020.32(k) at no charge.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the GEHC OEC service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO